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REPLY TO Wilmington Office

September 21, 2005

**VIA HAND DELIVERY**

The Honorable Kent A. Jordan  
U.S. District Court for the District of Delaware  
844 North King Street  
Wilmington, Delaware 19801

Re: **STATUS REPORT**  
*Glaxo Group Limited v. Teva Pharmaceuticals USA, Inc. et al.*,  
Civil Action No. 04-171-KAJ

Dear Judge Jordan:

We represent Plaintiff patentee, Glaxo Group Limited ("Glaxo"), and write to inform Your Honor of the present status of this patent infringement litigation in anticipation of the October 7, 2005 telephone status conference. This is an action for patent infringement under the Hatch-Waxman Act where plaintiff Glaxo accuses defendants' generic ranitidine hydrochloride oral syrup product of infringing the claims of Glaxo's U.S. Patent No. 5,068,249 ("the '249 patent").

**1. Teva's Document Production Failure**

**a. Documents Requested**

Defendants have made little progress in pursuing document discovery requests by Glaxo since our June 30th discovery teleconference, and Glaxo still has not received the documents from defendant Teva Pharmaceuticals USA, Inc. and its Israel parent Teva Pharmaceutical Industries Limited ("Teva") that we have been trying to obtain for the past twelve months. Teva still has not produced the documents that Teva agreed should be produced, (see Transcript ("Tr.") at pp. 9-11 (Exh. A)) and that we believe were required to be produced, pursuant to the June 30, 2005 teleconference, particularly:

- (i) the testing and development reports and laboratory notebooks relating to the formulation of ranitidine hydrochloride oral syrup (both [REDACTED] formulations);

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- (ii) experimental stability data and analyses for ranitidine oral syrup batches 3G-0431, 1853-005, 1853-015, 1853-017, 3213PD and 399-01 through 399-10 (formulations utilizing varying concentrations of [REDACTED]);
- (iii) the files and documents of Subrata Mazumder, the chief formulator of Teva's ranitidine oral syrup product; and
- (iv) the preformulation information package for ranitidine oral syrup.

This information is relevant to [REDACTED] ranitidine stabilizing properties – the only claim limitation disputed by Teva on the question of Teva's infringement of the '249 patent claims, as was stipulated by Teva's counsel during the June 30, 2005 teleconference. (Exh. A at p. 5:3-25). Glaxo repeatedly has identified these specific documents, and others, most recently in letters dated September 13 and 14, 2005, in two letters dated June 6, 2005, following the depositions of a Teva witness and a Novopharm witness, in a letter dated June 20, 2005, and in our June 28, 2005 letter to the Court, which was the subject of our June 30th teleconference. (Letters attached as Exhs. B, C, D, E, F and G). There is no excuse for Teva's failure to produce clearly relevant documents identified in the attached letters, which Teva agrees are relevant and should be produced! (Exh. A at pp. 9:23-11:21). At this late juncture of the case, after repeated, specific requests by Glaxo spanning twelve months, Teva has failed to act in good faith and has not produced any additional documents since our June 30th conference:

"THE COURT: . . . [t]his is a dispute about whether good faith efforts have and are continuing to take place to obtain concededly relevant documents, and you folks need to get on the same page and talk to each other about how to make that happen. And I expect just exactly that, discussion and good faith efforts to make stuff happen."

(Exh. A at p. 11: 13-19). It has not happened, despite Glaxo's urgent, repeated requests for Teva to produce the documents at issue.

**b. Teva's Pharmascience Excuse**

During our June 30th teleconference with the Court, we were advised by Teva's counsel for the first time that requested documents were allegedly no longer in Teva's possession, but rather were in possession of a third-party Canadian company. (Exh. A, at pp. 10:21-11:7). Since June 30th, Glaxo has been urgently attempting to obtain documents from Pharmascience, a Canadian corporation that we were told had acquired a production facility where Teva's accused ranitidine hydrochloride oral syrup formulations were developed, tested, and produced. After informal requests made by Glaxo to Pharmascience were rebuffed, Glaxo obtained a Letter of Request from Your Honor on August 2, 2005 asking the Canadian court to compel Pharmascience to produce the documents. Pharmascience, however, has refused to produce the documents and has filed a motion to quash the subpoena that was issued by the Canadian court pursuant to Your Honor's Letter of Request. Pharmascience has also indicated that they will invoke the *Canadian Business Concerns Records Act*, R.S.Q.c.D.-12, to completely block the production of any documents to Glaxo and the examination of any witness.

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Glaxo's only option now would be to challenge the constitutionality of the Act, a process that could take well over a one year. Pharmascience's position was reaffirmed at a hearing that was conducted by the Canadian Court on Friday, September 16, 2005.

Glaxo has also requested that Teva (or its corporate affiliate, Novopharm) seek return of what are in essence Teva (Novopharm) documents from Pharmascience; Teva has said it is "checking" but has not produced any documents or further correspondence to Pharmascience making such requests. Glaxo seeks these documents because they are potential evidence of infringement and of the validity and nonobviousness of the '249 patent. *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265, 284-87 (D. Md. 1998). The choices made in the formulation and development of the accused product and the alternative pathways tried and abandoned (e.g., unsuccessful efforts to design around the patented invention) are key indicia of infringement and validity. *Id.* Teva is hiding behind Pharmascience's Canadian domicile to avoid its discovery obligations.

### **c. Teva's Failure to Update Its ANDA Stability Data**

We also have been requesting, without success, that Teva, as is its obligation to supplement discovery responses, update its production of on-going stability testing and data for its ANDA batch of ranitidine oral syrup. The FDA requires that all applicants, including Teva, perform both accelerated and room-temperature stability studies on the product for which the applicant seeks approval. Stability measurements are taken periodically (e.g., every three months for room temperature stability studies) and the updated testing and data is provided to FDA. Teva must have this information, but has so far failed to produce it to Glaxo. Updated discovery of Teva's ongoing stability testing data for its ANDA product is, therefore, important for evaluation in connection with the submission of a Rule 26(a) expert report.

## **2. Depositions**

Glaxo has taken two depositions, one of a Novopharm witness and one of a Teva witness, both related to the limited documents related to the formulation work. Numerous discovery requests from both of these depositions remain unanswered. (See Exh. H). Due to the incomplete document production by Teva, including twelve months of unfulfilled promises of producing the requested documentation, we have refrained from taking additional depositions of Teva. Because the **November 2, 2005 deadline for submitting initial expert reports** pursuant to Rule 26(a) is fast approaching, Glaxo has noticed additional depositions of four Teva witnesses as well as two 30(b)(6) depositions in October, although Teva has not yet confirmed the deposition dates requested except for S. Mazumder on October 14. If any additional documents are produced after the depositions, these depositions will have to be continued and taken a second time at Teva's expense.

## **3. Proposed Scheduling Modification**

The parties are jointly proposing a short extension of the dates for submitting initial and rebuttal expert reports (to December 19, 2005 and January 16, 2006) and for concluding all discovery (February 13,

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2006), a copy of the signed stipulation is attached. (See Exh. I). Because of the limited time remaining, we are fearful that Teva has effectively sabotaged the discovery schedule and that meeting even this modified discovery schedule is contingent upon receiving the requested and admittedly relevant documents immediately, but we have no confidence that Teva will make it happen:

THE COURT: . . . Mr. Murphy . . . is there anything else we need to address while we're all on the line together?

MR. MURPHY: No, Judge. Only to note that we're running short on time to resolve these issues. And so we will try. We would ask for cooperation to do this as quickly as possible so we don't run into the discovery cutoff date.

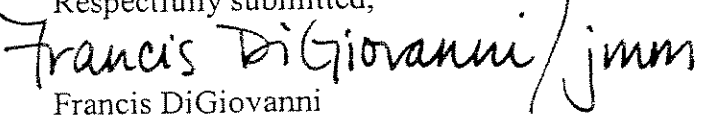
THE COURT: I'm sure you are going to get it; right, Mr. Schuman?

MR. SCHUMAN: Yes. We're motivated to move fast, Your Honor.

Far from moving fast, Teva has done little or nothing at all to assist Glaxo in obtaining the requested documents. We request that the Court order the extended dates jointly proposed by the parties subject to Glaxo reserving its right to request a further extension to obtain the requested documents. In the alternative, Glaxo renews its request that the Court consider an appropriate sanction (e.g., entry of a Judgment of patent infringement) under Fed. R. Civ. P. 37(b) and (c) against Teva.

#### 4. The Pharmadyne Discovery

Glaxo has received the objections of Teva with respect to the designated deposition and trial testimony of third-party witnesses who formulated Pharmadyne's infringing ranitidine oral solution using [REDACTED] Drs. Anita K. Runyan, Prasad Gullapalli and Nitin Pathak, who testified to the stabilizing effect of [REDACTED] on ranitidine in an oral syrup formulation. We are reviewing these objections and intend to take whatever action is necessary to ensure the admissibility of this evidence against Teva.

Respectfully submitted,  
  
Francis DiGiovanni

cc: Clerk of the Court (by hand)  
Josy W. Ingersoll, Esq. (by hand)  
Mark D. Schuman, Esq. (via Federal Express)  
Brian P. Murphy, Esq. (via Federal Express)